

### **REMARKS**

This amendment is responsive to the Office Action dated January 5, 2005. Applicant has amended claim 17 and canceled claim 21. Claims 1-11, 17 and 18 are pending.

#### **Claim Rejection Under 35 U.S.C. § 102**

In the Office Action, the Examiner rejected claims 1-3, 5-7, 9-11, 17, 18 and 21 under 35 U.S.C. 102(b) as being clearly anticipated by Dickhudt et al. (USPN 4,257,429). Applicant respectfully traverses the rejection to the extent such rejection may be considered applicable to the amended claims. Dickhudt et al. fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. 102(b), and provides no teaching that would have suggested the desirability of modification to include such features.

Dickhudt et al. fails to teach or suggest an implantable neurological stimulation lead comprising a lead body having a proximal end, a distal end, and a lumen, a stylet wire configured for insertion into the lumen, and a stylet handle connected to the stylet wire, wherein the stylet handle defines a lead carrier with a channel-like recess to receive the lead body when the lead body is pushed laterally into the recess, and includes one or more members that protrude into the channel-like recess to hold the lead body at any selected point along the lead body between the body distal end and the body proximal end, as recited by Applicant's claims 1-4.

Similarly, with respect to claim 5, the applied reference fails to describe an implantable neurological stimulation lead comprising a lead body having a proximal end, a distal end, and a stylet lumen, a stylet wire configured for insertion into the lumen, and stylet handle means for holding the lead body selectively connected to the stylet wire at any selected point along the lead body between the body distal end and the body proximal end, wherein the stylet handle means defines a lead carrier with a channel-like recess to receive the lead body when the lead body is pushed laterally into the channel-like recess, and includes one or more members that protrude into the channel-like recess to hold the lead body.

Dickhudt et al. also lacks any teaching that would have suggested a stylet for an implantable neurological stimulation lead comprising a stylet wire configured for insertion into a stylet lumen to stiffen a lead body, and a stylet handle connected to the stylet wire, wherein the

stylet handle defines a lead carrier with a channel-like recess to receive the lead body when the lead body is pushed laterally into the channel-like recess, and includes one or more members that protrude into the channel-like recess to hold the lead body at any selected point along the lead body between a distal end and a proximal end of the lead body, as recited by claims 6-8.

Further, contrary to the requirements of claim 9, Dickhudt et al. does not disclose a stylet for an implantable neurological stimulation lead comprising a stylet wire configured for insertion into a stylet lumen, and a means for holding the lead body selectively connected to the stylet wire, the means for holding defining a channel-like recess to receive the lead body when the lead body is pushed laterally into the channel-like recess, and including one or more members that protrude into the channel-like recess to hold the lead body at any selected point along the lead body between a distal end of the lead body and a proximal end of the lead body.

With respect to claims 10 and 11, the applied reference fails to teach or suggest a method comprising aligning a stylet wire with a stylet lumen of a lead body proximal end, inserting the stylet wire into the stylet lumen, stopping insertion of the stylet wire when the stylet wire contacts a stylet stop in the stylet lumen of a lead body distal end, inserting the lead body in a stylet handle lead carrier, and holding the lead body at any selected point along the lead body between a lead body distal end of and the lead body proximal end within a channel-like recess located in the stylet handle lead carrier when the lead body is pushed laterally into the channel-like recess, while the stylet wire remains in contact with the stylet stop in the stylet lumen in the lead body distal end, wherein the stylet handle lead carrier further includes one or more members that protrude into the channel-like recess to hold the lead body.

Furthermore, Dickhudt et al. does not describe a device comprising a stylet wire for insertion into a stylet lumen in a neurostimulation lead, and a stylet handle connected to the stylet wire, the stylet handle having a lead carrier to hold the lead at a selected point along the lead, wherein the lead carrier defines a channel-like recess to receive the lead when the lead is pushed laterally into the channel-like recess, and one or more members that extend into the channel-like recess, and wherein the stylet handle includes a lead opening to accommodate the lead and permit the stylet handle to be moved toward a distal end of the lead, as recited by amended claims 17 and 18.

In support of the rejection under section 102(b), the Examiner referred to Figures 1-3 of Dickhudt et al. and stated that “the groove 15, which is being read as the ‘channel-like recess,’ has fingers 16 extending into the channel that grab the lead body.” However, Dickhudt et al. fails to teach or suggest a means or a stylet handle for holding a lead body at any selected point along the lead body between a distal end of the lead body and a proximal end of the lead body, as required by Applicant’s claims 1-11.

On the contrary, Dickhudt et al. describes an engagement means for holding a lead body only at a proximal end of the lead body. For example, Dickhudt et al. teaches a lead engagement means (12) spaced from a knob (11) in a direction generally along a stylet (10), the lead engagement means formed of a body member (14) having a groove (15). Dickhudt et al. states, “[t]he lead body 17 should terminate in the space intermediate the knob 11 and the body member 14,” Col. 2, ll. 61-63. Dickhudt goes on to state that the lead may terminate at any point between the knob (11) and the body member (14), Col. 3, ll. 9-13.

As can be seen, Dickhudt et al. teaches holding a lead body at a portion of the proximal end of the lead body that falls between the knob and the engagement means of the lead placement system. Therefore, the device described by Dickhudt et al. is not capable of holding a lead body at any selected point along the lead body between a distal end and a proximal end of the lead body. In view of this difference, Dickhudt et al. does not anticipate the requirements of claims 1-11.

In addition, Dickhudt et al. does not teach or suggest a stylet handle including a lead opening to accommodate the lead and permit the stylet handle to be moved toward a distal end of the lead, as required by Applicant’s amended claims 17 and 18. Dickhudt et al. makes no mention of a lead opening to allow a lead body to extend through the knob (11) and terminate outside of the space intermediate the knob (11) and the body member (14). Dickhudt et al. provides no structural embodiment that would allow movement of the lead placement system toward the distal end of the lead body and does not suggest engaging the lead body closer to a distal end of the lead body.

Dickhudt et al. fails to disclose each and every limitation set forth in claims 1-3, 5-7, 9-11, 17 and 18. For at least these reasons, the Dickhudt et al. reference does not support a prima

facie case of anticipation of Applicant's claims 1-3, 5-7, 9-11, 17 and 18 under 35 U.S.C. 102(b).  
Withdrawal of this rejection is requested.

**Claim Rejection Under 35 U.S.C. § 103**

In the Office Action, the Examiner rejected claims 4 and 8 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Dickhudt et al. Applicant respectfully traverses the rejection. The Dickhudt et al. reference fails to disclose or suggest the inventions defined by Applicant's claims, and provides no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

With reference to claims 4 and 8, Dickhudt et al. lacks any teaching that would have suggested a stylet release in the stylet handle, the stylet release having an engaged position where the stylet wire is coupled to the stylet handle and a disengaged position where the stylet wire is decoupled from the stylet handle creating a lead opening to permit the stylet handle to be moved toward the lead distal end without being encumbered by the stylet wire.

Dickhudt et al. states that the stylet may be "secured within the knob 11 during the molding process or may be otherwise secured," Col. 2, ll. 43-45. In support of the rejection, the Examiner stated that the latter option appears to allow for detachable coupling of the stylet to the handle, but even if not, it is common in the art to make the stylet detachable from the handle mechanism. The Examiner asserted that it would have been obvious to one skilled in the art to modify the Dickhudt et al. device to incorporate the detachable function in order to permit use of multiple stylets.

The statement from Dickhudt et al. relied upon by the Examiner simply allows a variety of methods to secure the stylet (10) within the knob (11). Dickhudt et al. makes no mention of not securing the stylet within the knob or detachably coupling the stylet to the knob. Furthermore, even if the Dickhudt et al. device were modified to make the stylet detachable from the handle mechanism, it would not result in Applicant's claimed invention. As described above, Dickhudt et al. does not teach or suggest a lead opening to allow the lead body to extend through the knob and terminate outside of the region between the knob and the engagement member. The Dickhudt et al. provides no structural embodiment that would allow movement of the lead

placement system toward the distal end of the lead body and does not suggest engaging the lead body closer to a distal end of the lead body.

For at least these reasons, the Dickhudt et al. reference does not support a prima facie case of obviousness with respect to Applicant's claims 4 and 8. Withdrawal of this rejection is respectfully requested.

### CONCLUSION

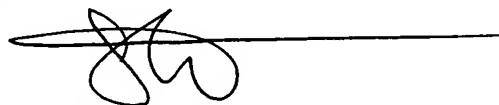
All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date:

By:

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